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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,094	10/04/2005	Richard R. Navarro	ZP193-05002	4200

22884 7590 01/07/2008

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ART UNIT	PAPER NUMBER
4153	

MAIL DATE	DELIVERY MODE
01/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,094	NAVARRO ET AL.	
	Examiner	Art Unit	
	Julianna N. Harvey	4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/21/2006, 04/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the details of the package of signal conditioning and amplification electronics (claims 20, 40, 62, 90, and 103), the internal coil (claim 104), the data storage element (claim 105), the micro battery (claim 108), the capacitor (claim 109), and the electronics needing no signal conditioning or amplification circuitry (claim 110) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

New corrected drawings for figures 26-29, in compliance with 37 CFR 1.121(d), are required in this application because the details of the drawings cannot be seen. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

The drawings for figures 26-29 are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference signs mentioned in the description: disc "10", appurtenances "27", upper endplate "20", lower endplate "30", and ball "91" (see paragraph 89 of the specification beginning on page 18). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 2, 54, 72, 82, 87, 90, 91, 100, and 111-114 are objected to because of the following informalities:

- Claim 2: "…said upper subplate." in line 5 should be "…said first subplate."
- Claim 54: "…third diameter." in line 8 should be "…fourth diameter."
- Claim 72: "…motion-limiting element…" in line 2 should be "…motion-limiting member…"
- Claim 82: "…said third diameter." in line 3 should be "…said fourth diameter."
- Claim 87: "…said aperture…" in line 4 should be "…said opening…"
- Claim 90: "…said second projection…" in lines 1-2 and line 4 should be "…said projection…"
- Claim 91: "…said second projection..." in lines 1-2 and line 3 should be "...said projection..."
- Claim 100: "…motion-limiting element…" in line 2 should be "…motion-limiting member…"
- Claim 111: "a polymeric cushion…" in line 17 should be "a visco-elastic cushion…"
- Claim 112: "a polymeric cushion…" in line 11 should be "a visco-elastic cushion…" and "…said upper and lower endplates…" in line 11 should be "… said first and second endplates…"

- Claim 113: "…said upper endplate…" in line 11 should be "…said first endplate…" and "…said lower endplate…" in line 12 should be "…said second endplate…"
- Claim 114: "a polymeric cushion…" in line 14 should be "a visco-elastic cushion…"

The examiner suggests these corrections to maintain consistency throughout the claims and with the specification and has read these corrections into the claims for the examination of this application. Appropriate correction is required.

Claims 104-107 and 109 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 104 and 105 attempt to further limit a package of signal conditioning and amplification electronics. Neither claim 104 nor claim 105 further limit claim 102, which does not include a package of signal conditioning and amplification electronics. Claims 106 and 107 are directed toward a method of retrieving data from the data storage element. Neither claim 106 nor claim 107 further limit claim 105, which is directed toward the physical structure of a disc prosthesis. Claim 109 attempts to further limit a power source for a data storage element. Claim 109 does not further limit claim 104, which does not include a data storage element. The examiner has read claims 104 and 105 as depending upon claim 103 instead of claim 102 and claim 109 as depending upon claim 105 instead of claim 104.

Claim Rejections - 35 USC § 112

35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 42, 64, and 92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

- Claims 22, 42, 64, and 92 recite the limitation that the flex circuit includes a load or pressure sensor. There is no mention in the specification of a load or pressure sensor.
- Claims 26, 68, and 96 recite the limitation that a single motion-limiting member is received in the first and second openings, which consist of a total of four holes, two in each endplate. There is no mention in the specification of a single motion-limiting member that does such. The examiner has read the modification "wherein ***said at least one*** motion-limiting member" into line 6 of the claims, which makes the claims consistent with the claims from which they depend and also makes them consistent with the specification.

These claims do not comply with the enablement requirement.

35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 12, 14, 20, 21, 27, 40, 41, 46, 49, 50, 52, 54, 56, 62, 63, 69, 78, 82, 84, 87, 90, 91, 97, 103-105, 108, 109, and 114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 12, 14, 20, 21, 27, 40, 41, 46, 49, 50, 52, 54, 56, 62, 63, 69, 78, 82, 84, 87, 90, 91, 97, 103-105, 108, 109, and 114 are rejecting for lacking sufficient antecedent basis.

- Claims 5, 52, and 78 recite the limitation "…said at least one opening of said second endplate has a third diameter at said lower surface of said second endplate and a fourth diameter at said upper surface of said second endplate..." in lines 1-3, which indicates that the opening in the endplate goes completely through the endplates from the lower surface to the upper surface. The examiner has read the claims as "…said at least one opening of said second endplate has a third diameter ***near*** said lower surface of said second endplate and a fourth diameter at said upper surface of said second endplate...", which is similar to claims 4, 51, and 77 as those do have proper antecedent basis.
- Claims 12 and 54 recite the limitation "…said at least one opening of said second endplate has a third diameter at said lower surface of said second endplate and a fourth diameter at said upper surface of said second endplate..." in lines 4-6,

which indicates that the opening in the endplate goes completely through the endplates from the lower surface to the upper surface. The examiner has read the claims as "…said at least one opening of said second endplate has a third diameter ***near*** said lower surface of said second endplate and a fourth diameter at said upper surface of said second endplate...", which is similar to "…said at least one opening of said first endplate has a first diameter ***near*** said upper surface of said first endplate and a second diameter at said lower surface of said first endplate…" in lines 2-4 and has proper antecedent basis.

- Claims 14, 56, and 84 recite the limitation "…said split ring assembly is fitted into said at least one opening at said upper surface of said first endplate and said at least one opening at said lower surface of said second endplate" in lines 2-4, which indicates more than one split ring assembly and that the openings in the endplates go completely through the endplates from the lower surfaces to the upper surfaces, neither of which was indicated in a previous claim. In the alternative, it could indicate a single split ring assembly that covers the entire length of the motion-limiting member, which is not supported by the specification. The examiner has read the claims as "…said at least one opening ***near*** said upper surface of said first endplate and said at least one opening ***near*** said lower surface of said second endplate...", which has proper antecedent basis, and that there are at least one split ring assemblies. The examiner requests Applicant to either correct these claims and/or the previous claims (claims 13, 55, and 83) to provide proper antecedent basis for these claims.

- Claims 20, 40, 62, and 90 recite the limitation "…said force or pressure transducer***s***…" in lines 3-4 whereas claims 19, 39, 61, and 89 are directed toward "…***a*** force or pressure transducer…"
- Claims 21, 41, 63, and 91 recite the limitation "…said force or pressure transducer***s***…" in lines 2-3 whereas claims 19, 39, 61, and 89 are directed toward "…***a*** force or pressure transducer…"
- Claims 27, 46, 69, and 97 recite the limitation "…said posterior portion of each of said first and second endplates…" in lines 1-2 though the previous claims mention that the disc, and not the endplates, has a posterior portion. The examiner has read the claims as they are but requests correction to bring the claims into compliance.
- Claim 49 recites the limitation "...said first projection of said first endplate..." in line 4 though claim 48 does not mention such a projection. The examiner has read the claim as it is but requests correction to bring the claim into compliance.
- Claim 50 recites the limitation "…said second projection of said second endplate…" in line 3 though claim 48 does not mention such a projection. The examiner has read the claim as it is but requests correction to bring the claim into compliance.
- Claim 82 recites the limitation "…said second diameter…said third diameter" in lines 2-3 though neither claim 74 nor claim 81 mentions either. The examiner has read the claim as it is, taking into account the previously-suggested

correction that "…said third diameter" read as "…said fourth diameter," but requests correction to bring the claim into compliance.

- Claim 87 recites the limitation "…said aperture of said lower surface..." in line 4 though the previous claims make no mention of such.
- Claim 103 recites the limitation "…said force or pressure transducer***s***…" in line 3 whereas claim 102 is directed toward "…***a*** force or pressure transducer..."
- Claim 104 recites the limitation "…said signal amplification electronics…" in lines 1-2 though claim 102 does not mention such electronics.
- Claim 105 recites the limitation "...said package of electronics..." in lines 1-2 though claim 102 does not mention such a package.
- Claims 108 and 109 recite the limitation "…said power source…" in lines 1-2 though the previous claims make no mention of such.
- Claim 114 recites the limitation "…said first projection…" in line 8 though there is no such projection in the claim. The examiner has read the claim as it is but requests correction to bring the claim into compliance.

There is insufficient antecedent basis for these limitations in the claims.

Regarding claim 104, the phrase "may be" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

The term "internal" in claim 104 is a relative term which renders the claims indefinite. The term "internal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In these claims, it is

unclear whether “internal” refers to internal to the package of electronics or internal to the disc.

The term "external" in claims 104 and 109 is a relative term which renders the claims indefinite. The term "external" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In these claims, it is unclear whether “external” refers to external to the package of electronics or external to the disc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 7, 18, 29, 32, 34, 38, 48, 49, 51, 60, 71, 74, 75, 77, 88, 99, and 111-114 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrington (US 5,893,889).

- Claim 1: Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper member “32” and collar “54” in figure 2) having an upper surface (see upper surface “36” of upper member or upper surface “56” of collar in figure 2) and a lower surface (see lower surface of upper member “32” or lower surface “58” of

collar in figure 2), said first endplate further comprising at least one opening (see opening surrounded by neck "57" in figure 2); a first projection (see tubular portion "50" or frustoconical surface of collar "54" in figure 2) extending from said lower surface of said first endplate terminating in a first distal end; a second endplate (see lower member "34" in figure 2) having an upper surface (see upper surface "44" in figure 2) and a lower surface (see lower surface "40" in figure 2), said second endplate further comprising at least one opening (see opening surrounding threaded post "45" in figure 2); a second projection (see frustoconical surface of lower member "34" in figure 2) extending from said upper surface of said second endplate and substantially aligned with said first projection, said second projection terminating at a second distal end to form a gap (see space between ends of tubular portion "50" or frustoconical surface of collar "54" and end of frustoconical surface of lower member "34" in figure 2) having a predetermined distance between said first distal end and said second distal end; at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2) received respectively in said at least one opening of said first endplate and said second endplate, said at least one motion-limiting member linking said first endplate to said second endplate and allowing only a predetermined amount of movement of said first endplate relative to said second endplate; and a visco-elastic cushion (see shock absorbing member "68" in figure 2) interposed between said first endplate and said second endplate, further comprising therein at least one cavity (see column 3, lines 58-63 focusing

on the "annular" shape of the shock absorbing member in conjunction with figure 2) in substantial alignment with said at least one opening in said first endplate and said second endplate through which said motion-limiting member may pass, and said at least one cavity surrounding said first and second projections.

- Claim 2: Harrington discloses the artificial intervertebral disc prosthesis of claim 1 wherein said first endplate (see upper member "32" and collar "54" in figure 2) further comprises a first subplate (see collar "54" in figure 2) having an upper surface (see upper surface "56" in figure 2) and a lower surface (see lower surface "58" in figure 2) and at least one opening therethrough (see opening surrounded by neck "57" in figure 2) for respectively receiving said at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2), wherein said first projection (see frustoconical surface of collar "54" in figure 2) of said first endplate extends from said lower surface of said upper subplate.
- Claim 4: Harrington discloses the artificial intervertebral disc prosthesis of claim 1 wherein said at least one opening (see opening surrounded by neck "57" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) has a first diameter (see diameter of opening around shock absorbing plug "69" in figure 2) near said upper surface (see upper surface "36" in figure 2) of said first endplate and a second diameter (see diameter of opening at neck "57" in figure 2) at said lower surface (see lower surface "58" in figure 2) of said first endplate, wherein said first diameter is greater than said second diameter.

- Claim 7: Harrington discloses the artificial intervertebral disc prosthesis of claim 1 wherein said first projection (see tubular portion "50" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) is substantially cylindrically shaped.
- Claim 18: Harrington discloses the artificial intervertebral disc prosthesis of claim 1 wherein said upper surface (see upper surface "36" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) and said lower surface (see lower surface "40" in figure 2) of said second endplate (see lower member "34" in figure 2) further comprise appurtenances (see pins "38" and "42" in figure 2) that aid in securing the prosthesis to the adjacent vertebrae.
- Claim 29: Harrington discloses the artificial intervertebral disc prosthesis of claim 1 wherein said motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2) has a length slightly greater than the total distance between said lower surface (see lower surface "58" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) and said upper surface (see upper surface "44" in figure 2) of said second endplate (see lower member "34" in figure 2) when said prosthesis is at rest, allowing said motion-limiting member to move within said cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) when said prosthesis is subject to loads.
- Claim 32: Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper

member “32” and collar “54” in figure 2) having an upper surface (see upper surface “36” of upper member or upper surface “56” of collar in figure 2) and a lower surface (see lower surface of upper member “32” or lower surface “58” of collar in figure 2); a first projection (see tubular portion “50” or frustoconical surface of collar “54” in figure 2) extending from said lower surface of said first endplate terminating in a first distal end; a second endplate (see lower member “34” in figure 2) having an upper surface (see upper surface “44” in figure 2) and a lower surface (see lower surface “40” in figure 2); a second projection (see frustoconical surface of lower member “34” in figure 2) extending from said upper surface of said second endplate and substantially aligned with said first projection, said second projection terminating at a second distal end to form a gap (see space between ends of tubular portion “50” or frustoconical surface of collar “54” and end of frustoconical surface of lower member “34” in figure 2) having a predetermined distance between said first distal end and said second distal end; and a visco-elastic cushion (see shock absorbing member “68” in figure 2) interposed between said first and second endplates further comprising a cavity (see column 3, lines 58-63 focusing on the “annular” shape of the shock absorbing member in conjunction with figure 2) for receiving said first and second projections.

- Claim 34: Harrington discloses the artificial intervertebral disc prosthesis of claim 32 wherein said first projection (see tubular portion “50” in figure 2) of said first

endplate (see upper member “32” and collar “54” in figure 2) is substantially cylindrically shaped.

- Claim 38: Harrington discloses the artificial intervertebral disc prosthesis of claim 32 wherein said upper surface (see upper surface “36” in figure 2) of said first endplate (see upper member “32” and collar “54”) and said lower surface (see lower surface “40” in figure 2) of said second endplate (see lower member “34” in figure 2) further comprise appurtenances (see pins “38” and “42” in figure 2) that aid in securing the prosthesis to adjacent vertebrae.
- Claim 48: Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper member “32” and collar “54” in figure 2) having an upper surface (see upper surface “36” of upper member or upper surface “56” of collar in figure 2) and a lower surface (see lower surface of upper member “32” or lower surface “58” in figure 2), said first endplate further comprising at least one opening (see opening surrounded by neck “57” in figure 2); a second endplate (see lower member “34” in figure 2) having an upper surface (see upper surface “44” in figure 2) and a lower surface (see lower surface “40” in figure 2), said second endplate further comprising at least one opening (see opening surrounding threaded post “45” in figure 2); at least one motion-limiting member (see threaded post “45” with spherical upper end “46” in figure 2) received respectively in said at least one opening of said first and second endplates, said at least one motion-limiting member connecting said first endplate to said second endplate and allowing only

a predetermined amount of movement of said first endplate relative to said second endplate; and a visco-elastic cushion (see shock absorbing member "68" in figure 2) between said lower surface of said first endplate and said upper surface of said second endplate, further comprising therein at least one cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) in substantial alignment with said at least one opening in said first and second endplates through which said at least one motion-limiting member may respectively pass.

- Claim 49: Harrington discloses the artificial intervertebral disc prosthesis of claim 48 wherein said first endplate (see upper member "32" and collar "54" in figure 2) further comprises a first subplate (see collar "54" in figure 2) having an upper surface (see upper surface "56" in figure 2) and a lower surface (see lower surface "58" in figure 2) and at least one opening therethrough (see opening surrounded by neck "57" in figure 2) for respectively receiving said at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2), wherein said first projection (see frustoconical surface of collar "54" in figure 2) of said first endplate extends from said lower surface of said first subplate.
- Claim 51: Harrington discloses the artificial intervertebral disc prosthesis of claim 48 wherein said at least one opening (see opening surrounded by neck "57" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) has a first diameter (see diameter of opening around shock absorbing plug "69"

in figure 2) near said upper surface (see upper surface "36" in figure 2) of said first endplate and a second diameter (see diameter of opening at neck "57" in figure 2) at said lower surface (see lower surface "58" in figure 2) of said first endplate, wherein said first diameter is greater than said second diameter.

- Claim 60: Harrington discloses the artificial intervertebral disc prosthesis of claim 48 wherein said upper surface (see upper surface "36" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) and said lower surface (see lower surface "40" in figure 2) of said second endplate (see lower member "34" in figure 2) further comprise appurtenances (see pins "38" and "42" in figure 2) that aid in securing the prosthesis to adjacent vertebrae.
- Claim 71: Harrington discloses the artificial intervertebral disc prosthesis of claim 48 wherein said motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2) has a length slightly greater than the total distance between said lower surface (see lower surface "58" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) and said upper surface (see upper surface "44" in figure 2) of said second endplate (see lower member "34" in figure 2) when said prosthesis is at rest, allowing said motion-limiting member to move within said cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) when said prosthesis is subject to loads.
- Claim 74: Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper

member “32” and collar “54” in figure 2) having an upper surface (see upper surface “36” of upper member or upper surface “56” of collar in figure 2) and a lower surface (see lower surface of upper member “32” or lower surface “58” of collar in figure 2), said first endplate further comprising at least one opening (see opening surrounded by neck “57” in figure 2); a second endplate (see lower member “34” in figure 2) having an upper surface (see upper surface “44” in figure 2) and a lower surface (see lower surface “40” in figure 2), said second endplate further comprising at least one opening (see opening surrounding threaded post “45” in figure 2); a projection (see frustoconical surface lower member “34” in figure 2) extending from said upper surface of said second endplate terminating at a distal end to form a gap (see space between ends of tubular portion “50” or frustoconical surface of collar “54” and end of frustoconical surface of lower member “34” in figure 2) in an unloaded condition between said lower surface of said first endplate and said distal end; at least one motion-limiting member (see threaded post “45” with spherical upper end “46” in figure 2) received respectively in said at least one opening of said first endplate and said second endplate, said at least one motion-limiting member linking said first endplate to said second endplate and allowing only a predetermined amount of movement of said first endplate relative to said second endplate; and a visco-elastic cushion (see shock absorbing member “68” in figure 2) interposed between said first endplate and said second endplate, further comprising therein at least one cavity (see column 3, lines 58-63 focusing on the “annular” shape of

the shock absorbing member in conjunction with figure 2) in substantial alignment with said at least one opening in said first endplate and said second endplate through which said motion-limiting member may pass.

- Claim 75: Harrington discloses the artificial intervertebral disc prosthesis of claim 74 wherein said first endplate (see upper member "32" and collar "54" in figure 2) further comprises a first subplate (see collar "54" in figure 2) having an upper surface (see upper surface "56" in figure 2) and a lower surface (see lower surface "58" in figure 2) and at least one opening therethrough (see opening surrounded by neck "57" in figure 2) for respectively receiving said at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2).
- Claim 77: Harrington discloses the artificial intervertebral disc prosthesis of claim 74 wherein said at least one opening (see opening surrounded by neck "57" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) has a first diameter (see diameter of opening around shock absorbing plug "69" in figure 2) near said upper surface (see upper surface "36" in figure 2) of said first endplate and a second diameter (see diameter of opening at neck "57" in figure 2) at said lower surface (see lower surface "58" in figure 2) of said first endplate, wherein said first diameter is greater than said second diameter.
- Claim 88: Harrington discloses the artificial intervertebral disc prosthesis of claim 74 wherein said upper surface (see upper surface "36" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) and said lower

surface (see lower surface "40" in figure 2) of said second endplate (see lower member "34" in figure 2) further comprise appurtenances (see pins "38" and "42" in figure 2) that aid in securing the prosthesis to the adjacent vertebrae.

- Claim 99: Harrington discloses the artificial intervertebral disc prosthesis of claim 74 wherein said motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2) has a length slightly greater than the total distance between said lower surface (see lower surface "58" in figure 2) of said first endplate (see upper member "32" and collar "54" in figure 2) and said upper surface (see upper surface "44" in figure 2) of said second endplate (see lower member "34" in figure 2) when said prosthesis is at rest, allowing said motion-limiting member to move within said cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) when said prosthesis is subject to loads.
- Claim 111: Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper member "32" and collar "54" in figure 2) having an upper surface (see upper surface "36" of upper member or upper surface "56" of collar in figure 2) and a lower surface (see lower surface of upper member "32" or lower surface "58" of collar in figure 2), said first endplate further comprising at least one opening (see opening surrounded by neck "57" in figure 2) for receiving at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2); a first projection (see tubular portion "50" or frustoconical surface of collar "54"

in figure 2) extending from said lower surface of said first endplate terminating in a first distal end; a second endplate (see lower member "34" in figure 2) having an upper surface (see upper surface "44" in figure 2) and a lower surface (see lower surface "40" in figure 2), said second endplate further comprising at least one opening (see opening surrounding threaded post "45" in figure 2) for receiving at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2); a second projection (see frustoconical surface of lower member "34" in figure 2) extending from said upper surface of said second endplate and substantially aligned with said first projection, said second projection terminating at a second distal end to form a gap (see space between ends of tubular portion "50" or frustoconical surface of collar "54" and end of frustoconical surface of lower member "34" in figure 2) having a predetermined distance between said first distal end and said second distal end; at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2) received respectively in said at least one opening of said first endplate and said second endplate, said at least one motion-limiting member linking said first endplate to said second endplate and allowing only a predetermined amount of movement of said first endplate relative to said second endplate; and a polymeric cushion (see shock absorbing member "68" in figure 2) interposed between said first endplate and said second endplate, further comprising therein at least one cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) in

substantial alignment with said at least one opening in said first endplate and said second endplate through which said motion-limiting member may pass and at least one cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) surrounding said first and second projections.

- Claim 112: Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper member "32" and collar "54" in figure 2) having an upper surface (see upper surface "36" of upper member or upper surface "56" of collar in figure 2) and a lower surface (see lower surface of upper member "32" or lower surface "58" of collar in figure 2); a first projection (see tubular portion "50" or frustoconical surface of collar "54" in figure 2) extending from said lower surface of said first endplate and terminating in a first distal end; a second endplate (see lower member "34" in figure 2) having an upper surface (see upper surface "44" in figure 2) and a lower surface (see lower surface "40" in figure 2); a second projection (see frustoconical surface of lower member "34" in figure 2) extending from said upper surface of said second endplate and substantially aligned with said first projection, said second projection terminating at a second distal end to form a gap (see space between ends of tubular portion "50" or frustoconical surface of collar "54" and end of frustoconical surface of lower member "34" in figure 2) having a predetermined distance between said first distal end and said second distal end; and a polymeric cushion (see shock absorbing member "68" in

figure 2) interposed between said upper and lower endplates further comprising a cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) for receiving said first and second projections.

- Claim 113: Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper member "32" and collar "54" in figure 2) having an upper surface (see upper surface "36" of upper member or upper surface "56" of collar in figure 2) and a lower surface (see lower surface of upper member "32" or lower surface "58" of collar in figure 2), said first endplate further comprising at least one opening (see opening surrounded by neck "57" in figure 2) for receiving at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2); a second endplate (see lower member "34" in figure 2) having an upper surface (see upper surface "44" in figure 2) and a lower surface (see lower surface "40" in figure 2), said second endplate further comprising at least one opening (see opening surrounding threaded post "45" in figure 2) for receiving at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2); at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2) received respectively in said at least one opening of said first and second endplates, said at least one motion-limiting member connecting said first endplate to said second endplate and allowing only a predetermined amount of movement of said first endplate relative to said

second endplate; and a visco-elastic cushion (see shock absorbing member "68" in figure 2) between said lower surface of said upper endplate and said upper surface of said lower endplate, further comprising therein at least one cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) in substantial alignment with said at least one opening in said first and second endplates through which said at least one motion-limiting member may respectively pass.

- Claim 114: Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper member "32" and collar "54" in figure 2) having an upper surface (see upper surface "36" of upper member or upper surface "56" of collar in figure 2) and a lower surface (see lower surface of upper member "32" or lower surface "58" of collar in figure 2), said first endplate further comprising at least one opening (see opening surrounded by neck "57" in figure 2) for receiving at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2); a second endplate (see lower member "34" in figure 2) having an upper surface (see upper surface "44" in figure 2) and a lower surface (see lower surface "40" in figure 2), said second endplate further comprising at least one opening (see opening surrounding threaded post "45" in figure 2) for receiving at least one motion-limiting member (see threaded post "45" with spherical upper end "46" in figure 2); a projection (see frustoconical surface of lower member "34" in figure 2) extending from said upper surface of said second endplate and

substantially aligned with said first projection (see tubular portion "50" or frustoconical surface of collar "54" in figure 2), said projection terminating at a distal end to form a gap (see space between ends of tubular portion "50" or frustoconical surface of collar "54" and end of frustoconical surface of lower member "34" in figure 2) having a predetermined distance between said lower surface of said first endplate and said distal end; at least one motion-limiting member (see threaded post "45" with spherical end "46" in figure 2) received respectively in said at least one opening of said first endplate and said second endplate, said at least on motion-limiting member linking said first endplate to said second endplate and allowing only a predetermined amount of movement of said first endplate relative to said second endplate; and a polymeric cushion (see shock absorbing member "68" in figure 2) interposed between said first endplate and said second endplate, further comprising therein at least one cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) in substantial alignment with said at least one opening in said first endplate and said second endplate through which said motion-limiting member may pass.

As previously indicated, claims 1, 2, 4, 7, 18, 29, 32, 34, 38, 48, 49, 51, 60, 71, 74, 75, 77, 88, 99, and 111-114 are rejected as being anticipated by Harrington (US 5,893,889).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 5, 6, 8-12, 26, 33, 35-37, 50, 52-54, 68, 76, 78-82, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889).

- Claims 3, 5, 11, 12, 50, 52-54, 76, 78, 81, and 82: Harrington discloses the claimed invention (see claims 1, 48, and 74 above) but fails to teach that the second endplate comprises a second subplate with a second projection (claims 3, 50, and 76), that the second endplate has an opening where a third diameter is greater than a fourth diameter (claims 5, 52, and 78), that the motion-limiting member has a first and second enlarged portion at the first and second end (claims 11, 53, and 81), that the second endplate has an opening where a third diameter is greater than a fourth diameter and the second enlarged portion has a diameter greater than the fourth diameter (claims 12 and 54), and that the second enlarged portion has a diameter greater than the fourth diameter (claim 82). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Harrington's invention such that the lower half is essentially a mirror image of the upper half as doing so would allow for easier insertion of the device by eliminating the need for the surgeon to know which end is which. This would be accomplished by creating the second endplate such that

it resembles the first endplate (see upper member "32" and collar "54" in figure 2), comprising a second subplate with a second projection (claims 3, 50, and 76), and creating the motion-limiting member with an enlarged portion (see spherical upper end "46" in figure 2) at both the first and second ends (claims 11, 53, and 81). As a result of doing this, the second endplate would have an opening where a third diameter is greater than a fourth diameter and the second enlarged portion would have a diameter greater than the fourth diameter (claims 5, 12, 52, 54, 78, and 82).

- Claims 6, 8-10, 33, 35-37, and 79-80: Harrington discloses the claimed invention (see claims 1, 32, and 74 above) but fails to specify the extension distance of the first projection (claims 6 and 33), the radius of the first distal end (claims 8 and 35), the extension distance of the second projection (claims 9, 36, and 79), and the size of the gap between the first and second distal ends (claims 10, 37, and 80). It would have been obvious to one of ordinary skill in the art at the time the invention was made to create the device such that the first projection extends approximately one to three millimeters (claims 6 and 33), the first distal end has a radius of approximately two to 15 millimeters (claims 8 and 35), the second projection extends approximately three to six millimeters (claims 9, 36, and 79), and the gap between the first and second distal ends is approximately one to two millimeters (claims 10, 37, and 80) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

- Claims 26, 68, and 96: Harrington discloses the claimed invention (see claims 1, 48, and 74 above) but fails to teach the use of at least one motion-limiting member located in two openings, one in each endplate, that are disposed in opposite medial-lateral directions from a central point in the transverse plane and in posterior portions of the endplates. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Harrington's invention such that there was at least one (i.e., two in this case) motion-limiting members located in two openings disposed in opposite medial-lateral directions from a central point in the transverse plane as doing so would restrict the degree of medial-lateral displacement of the endplates relative to each other. It would have been further obvious to place the openings in the posterior portion of the endplates as doing so would make the device more suited to disc replacement of certain regions of the spinal column as it would allow a greater degree of displacement in one direction of the anterior-posterior axis as opposed to the other direction.

As previously indicated, claims 3, 5, 6, 8-12, 33, 35-37, 50, 52-54, 76, and 78-82 are unpatentable over Harrington (US 5,893,889).

Claims 13-17, 55-56, and 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Khovaylo (US 4,241,463). Harrington discloses the claimed invention but fails to teach that the disc includes a split ring assembly (claims 13, 55, and 83), that a split ring assembly is located in the openings in the endplates near the upper surface of the first endplate and near the

lower surface of the second endplate (claims 14, 56, and 84), that the lower diameter of the through-hole of the split ring assembly is smaller than the diameter of the opening in the first endplate at the lower surface (claims 15, 57, and 85), that the lower diameter of the through-hole of the split ring assembly is smaller than the diameter of the opening in the second endplate at the upper surface (claims 16, 58, and 86), and that the motion-limiting member has an enlarged portion at both ends where the diameter of the enlarged portions is greater than the lower diameter of the split ring assembly (claims 17, 59, and 87). Khovaylo teaches a split ring (see split ring "50" in figures 2-4) with a curved inner wall (see inner wall "60" in figures 3 and 4) for use in a ball replacement prosthetic joint.

- Claims 13, 55, and 83: It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a split ring assembly, as suggested by Khovaylo, in place of the curved neck (see neck "57" in figure 2 of Harrington) portion of the subplate as doing so is a simple substitution of known elements to obtain a predictable result.
- Claims 14, 56, and 84: It would have been further obvious to modify the Harrington/Khovaylo combination such that the lower half is essentially a mirror image of the upper half as doing so would allow for easier insertion of the device by eliminating the need for the surgeon to know which end is which. It would have been further obvious to modify the mirror-image Harrington/Khovaylo combination such that a split ring assembly is located in the openings in the endplates near the upper surface of the first endplate and near the lower surface

of the second endplate as doing so would bring the enlarged ends of the motion-limiting member (see spherical upper end "46" of threaded post "45" in figure 2 of Harrington) closer to the curved surface (see lower surface “51” in figure 2 of Harrington) thereby limiting the amount of compression of which the device is capable.

- Claims 15, 57, and 85: Taking into account the substitution of a split ring assembly, as suggested by Khovaylo, for the curved neck, as taught by Harrington, it would have been obvious for the diameter of the through-hole of the lower surface of the split ring assembly to be smaller than the diameter of the first opening because if it were not, the split ring assembly could not hold the enlarged portion of the motion-limiting member (see spherical upper end "46" of threaded post "45" in figure 2 of Harrington).
- Claims 16, 58, and 86: Taking into account the substitution of a split ring assembly, as suggested by Khovaylo, for the curved neck, as taught by Harrington in conjunction with the mirror-image combination, it would have been obvious for the diameter of the through-hole of the lower surface of the split ring assembly to be smaller than the diameter of the second opening because if it were not, the split ring assembly could not hold the enlarged portion of the motion-limiting member (see spherical upper end "46" of threaded post "45" in figure 2 of Harrington).
- Claims 17, 59, and 87: Taking into account the aforementioned modifications, it would have been obvious that the diameter of the enlarged ends of the

longitudinal motion-limiting member is larger than the diameter of the opening at the lower surface of the split ring assembly because if it were not, the split ring assembly could not hold the enlarged portion of the motion-limiting member in place.

As previously indicated, claims 13-17, 55-56, and 83-87 are unpatentable over Harrington (US 5,893,889) in view of Khovaylo (US 4,241,463).

Claims 19, 20, 39, 61, 63, 89, and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Ishikawa et al. (US 6,447,448 B1).

- Claims 19, 39, 61, and 89: Harrington discloses the claimed invention (see claims 1, 32, 48, and 74 above) but fails to teach a force or pressure transducer located within the prosthesis. Ishikawa et al. teach an intervertebral disc containing a ball sensor (see ball sensor "808" in figure 8) which is similar to the ball IC (see column 9, lines 56-57) that contains a force transducer (see force transducer "160" in ball IC "110" in figure 4A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Harrington with a force transducer as suggested by Ishikawa et al. as doing so provides means to monitor stress and compression forces to assure proper alignment of the vertebrae and the development of forces due to vertebral degeneration and disc malfunction (see column 9, lines 54-61 of US 6,447,448 B1).

- Claim 20: Harrington and Ishikawa et al. teach the claimed invention (see claim 19 above) but fail to teach that the second projection houses a portion of a package of signal conditioning and amplification electronics connected to transducers within the projection or at other locations around the second endplate. Ishikawa et al. teach that the ball IC (referred to in claim 19 above) contains a processor (see processor "140" in figure 4A) which digitizes (i.e., conditions) the sensor data (see column 7, lines 34-35) and a transmitter (see transmitter "150" in figures 4A and 4B) that contains an amplifier (see amplifier "458" in figure 4B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Harrington with a processor and an amplifier, as suggested by Ishikawa et al., as the processor digitizes the data to make it compatible with external data reception devices and the amplifier strengthens the data signal prior to signal output. It would have been further obvious to place such a package (the transducer, the processor, and the amplifier) within the second projection as doing so would protect the processor and amplifier from potential compression against the visco-elastic cushion (see shock absorbing member "68" in figure 2 of US 5,893,889) and allow the transducer to measure the pressure on the endplate without interference from the visco-elastic cushion.
- Claims 21 and 63: Harrington and Ishikawa et al. teach the claimed invention (see claims 19 and 61 above) but fail to teach that the second projection houses electronics connected to transducers within the projection or at other locations

around the second endplate. Ishikawa et al. teach that the ball IC (referred to in claims 19 and 61 above) contains a processor (see processor "140" in figure 4A) which digitizes (i.e., conditions) the sensor data (see column 7, lines 34-35) and a transmitter (see transmitter "150" in figures 4A and 4B) that contains an amplifier (see amplifier "458" in figure 4B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Harrington with a processor and an amplifier, as suggested by Ishikawa et al., as the processor digitizes the data to make it compatible with external data reception devices and the amplifier strengthens the data signal prior to signal output. It would have been further obvious to place such a package (the transducer, the processor, and the amplifier) within the second projection as doing so would protect the processor and amplifier from potential compression against the visco-elastic cushion (see shock absorbing member "68" in figure 2 of US 5,893,889) and allow the transducer to measure the pressure on the endplate without interference from the visco-elastic cushion.

- Claim 102: Harrington teaches an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate (see upper member "32" and collar "54" in figure 2) having an upper surface (see upper surface "36" of upper member or upper surface "56" of collar in figure 2) and a lower surface (see lower surface of upper member "32" or lower surface "58" of collar in figure 2), said first endplate further comprising at least one opening (see opening surrounded by neck "57" in figure 2) for receiving at least one motion-

limiting member (see threaded post “45” with spherical upper end “46” in figure 2); a first projection (see tubular portion “50” or frustoconical surface of collar “54” in figure 2) extending from said lower surface of said first endplate terminating in a first distal end; a second endplate (see lower member “34” in figure 2) having an upper surface (see upper surface “44” in figure 2) and a lower surface (see lower surface “40” in figure 2), said second endplate further comprising at least one opening (see opening surrounding threaded post “45” in figure 2) for receiving at least one motion-limiting member (see threaded post “45” with spherical upper end “46” in figure 2); a second projection (see frustoconical surface of lower member “34” in figure 2) extending from said upper surface of said second endplate and at least partially aligned with said first projection, said second projection terminating at a second distal end to form a gap (see space between ends of tubular portion “50” or frustoconical surface of collar “54” and end of frustoconical surface of lower member “34” in figure 2) having a predetermined distance between said first distal end and said second distal end; at least one motion-limiting member (see threaded post “45” with spherical upper end “46” in figure 2) received respectively in said at least one opening of said first endplate and said second endplate, said at least one motion-limiting member linking said first endplate to said second endplate and allowing only a predetermined amount of movement of said first endplate relative to said second endplate; and a visco-elastic cushion (see shock absorbing member “68” in figure 2) interposed between said first endplate and said second endplate, further

comprising therein at least one cavity (see column 3, lines 58-63 focusing on the "annular" shape of the shock absorbing member in conjunction with figure 2) in substantial alignment with said at least one opening in said first endplate and said second endplate through which said motion-limiting member may pass. Harrington fails to teach a force or pressure transducer located within the prosthesis. Ishikawa et al. teach an intervertebral disc containing a ball sensor (see ball sensor "808" in figure 8) which is similar to the ball IC (see column 9, lines 56-57) that contains a force transducer (see force transducer "160" in ball IC "110" in figure 4A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Harrington with a force transducer as suggested by Ishikawa et al. as doing so provides means to monitor stress and compression forces to assure proper alignment of the vertebrae and the development of forces due to vertebral degeneration and disc malfunction (see column 9, lines 54-61 of US 6,447,448 B1).

As previously indicated, claims 19, 39, 61, 89, and 102 are unpatentable over Harrington (US 5,893,889) in view of Ishikawa et al. (US 6,447,448 B1).

Claims 22, 42, 64, and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Ishikawa et al. (US 6,447,448 B1) further in view of Wanderman et al. (US 5,511,561) and Medical Electronics Manufacturing (hereinafter referred to as "MEM"; Dorren, Sonny, *Designing Compact Medical Devices with Flex Circuitry*). Harrington and Ishikawa et al. teach the claimed

invention (see claims 19, 39, 61, and 89 above) but fail to teach that the second endplate comprises a flex circuit that includes a load sensor (claims 42, 64, and 92) or a load or pressures sensor (claim 22) embedded onto the upper surface of the second endplate. Wanderman et al. teach a flex circuit that includes a load sensor (see column 5, lines 8-11). MEM teaches that flex circuits can be used in implanted medical devices (see the last sentence of the third paragraph on page 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention with a flex circuit that includes a load sensor, as suggested by Wanderman et al. and MEM, as flex circuits reduce the size of the package of electronics and have lower assembly costs. It would have been further obvious to embed the flex circuit onto the surface of one of the endplates as that would allow the sensor to measure the load on the visco-elastic cushion. As such, embedding the flex circuit onto the surface of the second endplate is obvious as it is just a matter of individual preference whether the circuit is located on the surface of the first or second endplate as both locations would provide the same data.

Claims 23, 27, 28, 43, 46, 47, 65, 69, 70, 93, 97, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Steffee (US 5,071,437).

- Claims 23, 43, 65, and 93: Harrington discloses the claimed invention (see claims 1, 32, 48, and 74 above) but fails to teach that the first and second endplates are made of a biocompatible material. Steffee teaches an intervertebral disc prosthesis where the endplates are biocompatible (see column

4, lines 43-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Harrington such that the endplates are made of a biocompatible material as suggested by Steffee as the body is less likely to have an adverse reaction to biocompatible implants.

- Claims 27, 28, 46, 47, 69, 70, 97, and 98: Harrington discloses the claimed invention (see claims 1, 32, 48, and 74 above) but fails to teach that the posterior portion of both the first and second endplates comprises a concave portion and posterior lobes (claims 27, 46, 69, and 97) and that the endplates have "D"-shaped external surfaces (claims 28, 47, 70, and 98). Steffee teaches an intervertebral disc prosthesis comprising first and second endplates, both with a concave portion and posterior lobes (see column 4, lines 26-29 in conjunction with figures 2 and 3) such that the external surfaces of the endplates (see upper rigid flat plate "12" and lower rigid flat plate "14" in figure 2) create a "D" shape (see figures 2 and 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Harrington such that the posterior portion of each endplate comprises a concave portion and posterior lobes, as disclosed by Steffee, resulting in "D"-shaped endplates as this configuration resembles that of a natural disc (see column 4, lines 26-32 of US 5,071,437).

As previously indicated, claims 23, 27, 28, 43, 46, 47, 65, 69, 70, 93, 97, and 98 are unpatentable over Harrington (US 5,893,889) in view of Steffee (US 5,071,437).

Claims 24, 44, 66, and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Steffee (US 5,071,437) further in view of Cauthen (US 6,179,874 B1). Harrington and Steffee (see claims 23, 43, 65, and 93 above) teach the claimed invention but fail to teach that the endplates are made from stainless steel, stainless steel alloys, titanium, titanium alloys, cobalt chromium molybdenum (hereinafter referred to as "CoCrMo") alloys, or composite materials. Steffee teaches that the endplates can be made of 316 LVM stainless steel (a stainless steel alloy), titanium, a titanium alloy, or a CoCrMo alloy (see column 4, lines 43-53). Cauthen teaches that the endplates can be made of zirconium oxide ceramic (a composite material) or stainless steel (see column 5, lines 23-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the endplates of the Harrington device from stainless steel, a stainless steel alloy, titanium, a titanium alloy, a CoCrMo alloy, or a composite material as suggested by Steffee and Cauthen because these materials are high-strength and biocompatible.

Claims 25, 45, 67, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Steffee (US 5,071,437) and Cauthen (US 6,179,874 B1) further in view of Kenna (US 4,714,469) and Wang et al. (US 4,714,468). Harrington, Steffee, and Cauthen (see claims 24, 44, 66, and 94 above) teach the claimed invention but fail to teach that the endplates are made from an alloy containing approximately 66% cobalt, approximately 28% chromium, and approximately 6% molybdenum. Kenna teaches an intervertebral disc device where the rigid body is made of Vitallium (see column 3, lines 59-63). A typical Vitallium

composition is 64.8% cobalt, 28% chromium, and 5.5% molybdenum (see column 1, lines 28-40 of US 4,714,468). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the endplates of the Harrington device from Vitallium as Vitallium has high corrosion resistance (see column 1, lines 28-30 of US 4,714,468).

Claims 30, 72, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Hedman et al. (US 4,759,769). Harrington discloses the claimed invention (see claims 1, 48, and 74 above) but fails to teach that the motion-limiting member is a cable. Hedman et al. teach a device where the motion-limiting member is a cable (see cables "110" in figure 9) with an enlarged portion (see end caps "114" in figure 9) at the ends. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the threaded post (motion-limiting member) of Harrington's device with a cable as suggested by Hedman et al. as doing so would provide more flexibility to the device.

Claims 31, 73, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view Hedman et al. (US 4,759,769) further in view of Fettel (US 4,057,857), Preissman (US 5,476,465), and Songer et al. (US 5,536,270). The Harrington/Hedman combination, as discussed under claims 30, 72, and 100, teaches the claimed device but fails to teach that the cable is made of a material selected from the group consisting of 316L stainless steel, MP35N, and Haynes 25. Fettel teaches a heart valve where, in one embodiment, a strut element, which is made of wire (see column 8, lines 3-8) takes the place of a rod (see column 8,

lines 3-8) that can be made of Haynes 25 (see column 8, lines 21-30). Preissman teaches a surgical cable crimp where the cable may be made of MP35N (see column 3, lines 45-48). Songer et al. teach a cable system to secure bone where the cable may be made of 316L stainless steel (see column 4, lines 55-61). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Harrington/Hedman combination such that the cable was made of Haynes 25, as suggested by Fettel, MP35N, as suggested by Preissman, or 316L stainless steel, as suggested by Songer et al., as these three materials have high corrosion resistance.

Claims 40, 41, 62, 90, 91, 103, and 105-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Ishikawa et al. (US 6,447,448 B1) further in view of Kovacevic (US 5,197,488).

- Claims 40, 62, and 90: Harrington and Ishikawa et al. teach the claimed invention (see claims 39, 61, and 89 above) but fail to teach that the second projection houses a portion of a package of signal conditioning and amplification electronics connected to transducers within the projection and at other locations around the second endplate. Ishikawa et al. teach that the ball IC (referred to in claims 39, 61, and 89 above) contains a processor (see processor “140” in figure 4A) which digitizes (i.e., conditions) the sensor data (see column 7, lines 34-35) and a transmitter (see transmitter “150” in figures 4A and 4B) that contains an amplifier (see amplifier “458” in figure 4B). Kovacevic teaches a device where the transducer is located on a plate positioned between the two endplates (see transducer “14” positioned between the tibial platform "13" and the tibial cover

plate "16" in figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Harrington and Ishikawa et al. with a processor and an amplifier, as suggested by Ishikawa et al., as the processor digitizes the data to make it compatible with external data reception devices and the amplifier strengthens the data signal prior to signal output. It would have been further obvious to place such a package (the transducer, the processor, and the amplifier) within the second projection as doing so would protect the processor and amplifier from potential compression against the visco-elastic cushion (see shock absorbing member "68" in figure 2 of US 5,893,889) and allow the transducer to measure the pressure on the endplate without interference from the visco-elastic cushion. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place a transducer between the two plates, as suggested by Kovacevic, as this would allow the measurement of the pressure on the visco-elastic cushion (see shock absorbing member "68" in figure 2 of US 5,893,889). It would have been further obvious to place this transducer on the surface of the second endplate as it would still be in contact with the visco-elastic cushion and could easily be connected to the amplifier and processor located within the second projection, eliminating the need to include another amplifier and processor that could potentially be damaged from compression between the visco-elastic cushion and the second endplate.

- Claims 41 and 91: Harrington and Ishikawa et al. teach the claimed invention (see claims 39 and 89 above) but fail to teach that the second projection houses electronics connected to transducers within the projection and at other locations around the second endplate. Ishikawa et al. teach that the ball IC (referred to in claims 39 and 89 above) contains a processor (see processor “140” in figure 4A) which digitizes (i.e., conditions) the sensor data (see column 7, lines 34-35) and a transmitter (see transmitter “150” in figures 4A and 4B) that contains an amplifier (see amplifier “458” in figure 4B). Kovacevic teaches a device where the transducer is located on a plate positioned between the two endplates (see transducer “14” positioned between the tibial platform "13" and the tibial cover plate "16" in figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Harrington and Ishikawa et al. with a processor and an amplifier, as suggested by Ishikawa et al., as the processor digitizes the data to make it compatible with external data reception devices, and the amplifier strengthens the data signal prior to signal output. It would have been further obvious to place such a package (the transducer, the processor, and the amplifier) within the second projection as doing so would protect the processor and amplifier from potential compression against the visco-elastic cushion (see shock absorbing member "68" in figure 2 of US 5,893,889) and allow the transducer to measure the pressure on the endplate without interference from the visco-elastic cushion. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

to place a transducer between the two plates, as suggested by Kovacevic, as this would allow the measurement of the pressure on the visco-elastic cushion (see shock absorbing member "68" in figure 2 of US 5,893,889). It would have been further obvious to place this transducer on the surface of the second endplate as it would still be in contact with the visco-elastic cushion and could easily be connected to the amplifier and processor located within the second projection, eliminating the need to include another amplifier and processor that could potentially be damaged from compression between the visco-elastic cushion and the second endplate.

- Claims 103, 105, 108 and 109: Harrington and Ishikawa et al. teach the claimed invention (see claim 102 above) but fail to teach that the second projection houses a package of signal conditioning and amplification electronics connected to transducers within the projection and at other locations around the second endplate (claim 103), that the package includes a data storage element (claim 105), that the power source is a micro battery (claim 108) and that the power source is a capacitor (claim 109). Ishikawa et al. teach that the ball IC (referred to in claim 102 above) contains a processor (see processor “140” in figure 4A) which digitizes (i.e., conditions) the sensor data (see column 7, lines 34-35) and a transmitter (see transmitter “150” in figures 4A and 4B) that contains an amplifier (see amplifier “458” in figure 4B). Ishikawa et al. also teach that the processor can be a digital signal processor, which is a type of microprocessor and as such is capable of data storage (see column 6, lines 15-20). Ishikawa et

al. further teach that the ball IC (referred to in claim 102 above) can be powered by a miniature battery (see column 5, lines 20-24) or, alternatively, by a capacitor (see column 4, line 66 through column 5, line 3). Kovacevic teaches a device where the transducer is located on a plate positioned between the two endplates (see transducer “14” positioned between the tibial platform "13" and the tibial cover plate "16" in figure 1). Regarding claim 103, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Harrington with a processor and an amplifier, as suggested by Ishikawa et al., as the processor stores data (claim 105) and digitizes the data to make it compatible with external data reception devices and the amplifier strengthens the data signal prior to signal output. It would have been further obvious to place such a package (the transducer, the processor, and the amplifier) within the second projection as doing so would protect the processor and amplifier from potential compression against the visco-elastic cushion (see shock absorbing member "68" in figure 2 of US 5,893,889) and allow the transducer to measure the pressure on the endplate without interference from the visco-elastic cushion. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place a transducer between the two plates, as suggested by Kovacevic, as this would allow the measurement of the pressure on the visco-elastic cushion (see shock absorbing member "68" in figure 2 of US 5,893,889). It would have been further obvious to place this transducer on the surface of the second endplate as it would still be in

contact with the visco-elastic cushion and could easily be connected to the amplifier and processor located within the second projection, eliminating the need to include another amplifier and processor that could potentially be damaged from compression between the visco-elastic cushion and the second endplate. Regarding claims 108 and 109, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a micro battery as a power source for the electronics package, as suggested by Ishikawa et al., or a capacitor as a power source, also as suggested by Ishikawa et al., as there are but a finite number of ways to power micro-electronic devices.

- Claims 106 and 107: Neither the retrieval of data by a preset sampling routine (claim 106) nor the retrieval of data via internet (claim 107) further limit the structure of the claimed apparatus as they are both directed toward a method of data retrieval. As such, these claims are rejected based on the analysis for claim 105, the claim on which both of these are dependent.
- Claim 110: Harrington and Ishikawa et al. teach the claimed invention (see claim 102 above) but fail to teach that the transducer is connected to electronics that do not need signal conditioning or amplification circuitry. Kovacevic teaches a joint prosthesis where the transducer is connected to piezoelectric sensors (see column 5, lines 25-30), which do not require signal conditioning or amplification circuitry. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Harrington and Ishikawa et al. device such that the transducer is connected to piezoelectric sensors, as suggested by

Kovacevic, as piezoelectric devices require little to no energy input and require less space than a package of electronics capable of providing signal conditioning and amplification.

As previously indicated, 40, 41, 62, 90, 91, 103, and 105-110 are unpatentable over Harrington (US 5,893,889) in view of Ishikawa et al. (US 6,447,448 B1) further in view of Kovacevic (US 5,197,488).

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Ishikawa et al. (US 6,447,448 B1) further in view of Kovacevic (US 5,197,488) and Donovan (US 4,688,000). Harrington, Ishikawa et al., and Kovacevic teach the claimed invention (see claim 103 above) but fail to teach that the signal amplification electronics include an internal coil that may be excited by an inductively coupled external coil. Donovan teaches that signal amplification can be accomplished through the use of an induction coil (see column 3, line 66 through column 4, line 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an induction coil as part of the amplifier, as suggested by Donovan, as the use of an induction coil is one of a finite number of ways to accomplish signal amplification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 107, which depends from claims 102, 103, and 105, is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 15 of copending Application No. 10/863,858. Although the conflicting claims are not identical, they are not patentably distinct from each other.

As previously stated, the examiner has read claim 105 as depending upon claim 103 instead of claim 102 as it further limits the package of data storage electronics first introduced in claim 103.

- Claim 1 of 10/863,858: A prosthetic implant for implanting in a body, comprising: a support member for interfacing with bone (it is inherent that the first and second endplates of claim 102 are support members and it is clear that both interface with vertebrae); at least one sensor for measuring parameters associated with the support member (it is obvious from claim 103 that the force or pressure transducers that are placed within the projection that extends from the second endplate measure parameters associated with said endplate); a memory for storing the output of the at least one sensor for later retrieval (the data storage element of claim 105); and a telemetry device operable to transmit the contents of said memory in response to an external request external to the body (it is obvious that claim 107 includes a telemetry device as a telemetry device transmits data to a remote site).
- Claim 15 of 10/863,858: The prosthetic implant of claim 1, wherein the at least one sensor measures forces associated with said support member (it is obvious from claim 103 that the force or pressure transducers that are placed within the projection that extends from the second endplate measure forces associated with said endplate).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JNH
12/17/07

/J.N.H./

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